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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,011	07/23/2001	Mark Leslie Smythe	065064/0135	9310
22428	7590	10/18/2004		
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER CLOW, LORI A	
			ART UNIT 1631	PAPER NUMBER

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/830,011	Applicant(s) SMYTHE ET AL.	
	Examiner Lori A. Clow, Ph.D.	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,16,17,27,28,31-38 and 40-44 is/are pending in the application.
 4a) Of the above claim(s) 1,3,4,16,17 and 39 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31-34,36-38 and 40-44 is/are allowed.
- 6) ☒ Claim(s) 27, 28, and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 23 July 2004, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1, 3, 4, 16, 17, 27, 28, 31-38, 40-44 are currently pending. Claims 1, 3, 4, 16, 17, and 39 are withdrawn for being directed to a non-elected invention. Applicant is reminded that a complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 27 and 28 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Claims 27 and 28 are directed to a computer-readable medium encoded with a program for searching a protein database. However it is not clear what result is produced by the said computer-readable medium. The "usefulness" of searching a protein database that includes the steps of comparing a query and identifying hits by the recited steps is not apparent, as there is no recited outcome of the said computer-readable medium for searching a protein database. Claim 28 does not rectify the problem by further comparing each hit to select one or more hits having 3D structural similarity to a sample protein because it is still not apparent what the usefulness of such a program is. It is noted that in order for this program to be useful for these

purposes, other information is required, such as identification or engineering of an actual target or framework protein or by following detailed steps that utilize specific parameters to perform the methods of the program. Utilities that carry out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities (See MPEP 2107.01). Further, as set forth in *Brenner v. Mason* (148 USPQ 689 (1966)) and *In re Ziegler* (26 USPQ2d 1600), the "usefulness" of an invention must be immediately apparent to those familiar with the technological field of the invention. As further research, mathematical calculations, and method steps would be required to "use" the instant method and system the apparent result of the method and system is not "immediately useful" and lacks utility.

Claim Rejections - 35 USC § 112

New Matter-112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 27 and 28 recite "a computer-readable medium encoded with a program". However, the specification fails to disclose a "computer-readable medium". The specification discloses only a computer program. For example, at page 10, lines 18-20, the specification states

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that the instant invention “resides in a computer program”, but fails to describe that this program is contained in a computer-readable medium.

Vague and Indefinite-112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 recites “a computer-readable medium encoded with a program which filters said hits identified at step (ii) of claim 27...” It is unclear if this claim is intended to be a further limitation of claim 27 or if it is a completely different product. Clarification is requested.

Claim 35 recites ““protein has increased structural similarity compared to said sample protein”. It is unclear what is meant by increased structural similarity? How could a protein have an increased similarity to another protein? Perhaps Applicant intends that the claim read “increased structural stability” as is disclosed on page 22 of the specification. Clarification is requested.

Allowable Subject Matter

Claims 31-34, 36-38, and 40-44 are allowable, as the prior art does not anticipate or fairly suggest a method of protein engineering including the steps recited in the claims.

Claims 27, 28, and 35 are rejected for the reasons set forth above.

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Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center Number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

MARJORIE MORAN
PATENT EXAMINER

October 14, 2004
Lori A. Clow, Ph.D.
Art Unit 1631

Lori Clow

Marjorie Moran
10/14/04